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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,058	04/10/2002	Florian Kern	100725-/Kreisler 1099-KGB	9559

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EXAMINER	
MOSHER, MARY	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,058	KERN ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *22 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *4-6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-3 and 7-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. **It is important that the abstract not exceed 150 words in length** since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it exceeds 150 words in length and is not narrative in form. Correction is required. See MPEP § 608.01(b).

Election/Restrictions

Applicant's election with traverse of Species 1, claim 2 in the reply filed on 3/22/2004 is acknowledged. The traversal is on the ground(s) that the claimed peptides all share a common utility, for example to induce the production of interferon-γ or TNF in CD8+ T cells. This is not found persuasive because peptides able to induce the production of interferon-γ in CD8+ T cells were known in the prior art, see e.g. Belz et al (PNAS 95:13812-13817, 1998), therefore this common utility does not qualify as a special technical feature which defines the invention over the prior art.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as excluding the elected species, there being no allowable generic or linking claim. Claims 1, 3, 7-16 have been examined only to the extent that they read upon the elected species, peptides comprising Glu Leu Arg Lys Met Met Tyr. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/22/2004.

Claim Rejections - 35 USC § 112

Claims 1-3 and 7-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for several reasons.

At lines 4-7, the claim defines R_N and R_C in sequence (I) as encompassing at least one additional amino acid. At lines 9-10, the claim discusses truncation of sequence (I). But since sequence (I) includes an unspecified number of unspecified amino acids at either end, the required "9 contiguous amino acids" can be made up entirely from the unspecified sequence within R_N or R_C; is this really the intent of the claim?

At line 11, the claim says "wherein said peptide derivatives essentially have the functionality of..." but does not define the functionality required, or define how much difference from the function is embraced by "essentially".

Line 16 duplicates line 15.

At lines 18-19, the term "i.e." renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See

MPEP § 2173.05(d). Also at lines 18-19, the claim recites the broad recitation "to induce the production..." and the claim also recites "especially from subject immunized with HCMV and having the appropriate HLA type," which is a narrower statement of the limitation. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In addition, if the functionality involves HLA presentation of the peptide, it is not clear what N-and C-terminal extensions are compatible with this.

For these reasons, it is not clear what functions the claimed "derivative" peptide must be capable of performing, and it is not clear what peptides are capable of performing the functions. This affects claims which depend from claim 1, and claims (e.g. claim 3) which share the same claim language.

In addition, line 13 of claim 1 defines SEQ ID NO:9 as "Glu Leu Arg Arg Lys Met Met Tyr Met," but claim 2 defines SEQ ID NO:9 as including "R_N Glu Leu Arg Arg Lys Met Met Tyr Met R_C." Which is correct? SEQ ID NO. 10 and 14 are similarly confused.

Claim 10 recites "The peptides...according to claim 1 as a medicament or diagnostic agent." It is not clear if this is meant as a product claim or a method claim. If this is a product claim, the recitation of intended use does not confer any definite limitation, and the claim is no different in scope from the parent claim. If this is a method claim, it is incomplete as there are no active steps recited.

Claims 12-13 are incomplete, as they lack a correlation step describing how the results of the assay allow for the determination of the response recited in the preamble. Claim 13 is also confusing because part b) is incomplete: "detecting whether the number of T cells that have been induced to produce interferon- or TNF- in CD8+ T cells." Detecting *what* regarding the number of induced T cells?

Claims 1, 3, 7-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nonapeptide truncations of SEQ ID NO:2, does not reasonably provide enablement for the full scope of derivatives and variants, or for the full scope of N-and C-terminal extensions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. These claims are drawn in part to variants which "essentially have the functionality" of specific peptides. As discussed above, it is not clear what is meant by the "functionality" or what enlargement of scope is meant by "essentially". Without an understanding of what functions the

peptides have to perform, one skilled in the art cannot define or make the full scope of the claimed functional peptides. In addition, if the functionality involves HLA presentation of the peptide, it is not clear what N-and C-terminal extensions are compatible with this.

Claims 11 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims involve vaccines. The specification provides little guidance regarding vaccines, and no working examples. Gonczol et al (Expert Opinion on Biological Therapy, 1:401-412, 2001) is cited as evidence of the state of the art several years later than applicant's claimed priority date. Gonczol states in the abstract that "All candidate vaccines will have to demonstrate that immunogenicity provides protection." This indicates that one skilled in the CMV vaccine art would not unquestioningly accept an unsupported assertion regarding the efficacy of a vaccine. Considering the state of the art even later than the claimed date of invention, the unpredictability of vaccine efficacy, the limited guidance and absence of working examples, it is concluded that undue experimentation would be required to use the vaccine as claimed.

Claims 1, 7-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the full scope of the claimed invention. These claims encompass peptide variants and derivatives which differ from a defined sequence by deletion, insertion, or substitution; the variants and derivatives are further required to share some functional similarity to the peptide of SEQ ID no. 2, 9, 10, or 14. Therefore these claims are drawn to a genus of peptides. Gautier et al (European Journal of Immunology 26:1110-1117, 1996) is cited as evidence that small variations in the sequence of an IE1 oligopeptide produce unpredictable changes in how they function with T cells. Therefore the genus embraces unpredictable species. The specification fully defines the structure of peptides which are truncations relative to SEQ ID no. 2, but does not fully define the structure of any deletion, insertion, or substitution variant. Considering the large number of possible species, the unpredictability of function, and the limited range of peptides which are reduced to practice in the specification, it is concluded that the specification does not contain an adequate written description for the full scope of the genus claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Alp et al (Journal of Virology 65:4812-4820, 1991). See Peptide 7 in the legend to Figure 2; this meets the claim requirements for R_N Asp Glu Leu Arg Arg Lys Met Met Tyr Met R_C.

Although the reference does not teach that the peptide induces IF-gamma or TNF-alpha in CD8+ T cells, this reasonably appears to be an inherent characteristic of the peptide, since it shares the critical sequence of applicant's SEQ ID NO. 10.

Claims 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Berencsi et al (Vaccine 14:369-374, 1996). Berencsi teaches DNA vector vaccines comprising the HCMV IE1 E4 exon, which encodes a sequence comprising SEQ ID No. 2. Since neither the specification or the claims makes clear how the size of N-and C-terminal extensions affect the functionality, the broadest reasonable interpretation of the claims includes polypeptides substantially larger than SEQ ID No. 2, including the IE1 polypeptide encoded by this vector.

Claims 1, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by He et al (Journal of General Virology 76:1603-10, 1995). He teaches HCMV IE1 protein, which comprises SEQ ID No. 2. As discussed above, the broadest reasonable interpretation of the claims includes polypeptides substantially larger than SEQ ID No. 2, including the IE1 protein disclosed by the reference.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

6/25/04

MARY E. MOSHER
PRIMARY EXAMINER
GROUP ~~1800~~ 1600